REMARKS

Claims 1-18 are pending in the instant application. Claims 7, 11-15 and 17 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants herein. Claims 1, 2, 3, 4, 5, 8, 10 and 16 have been amended. Support for these amendments is provided in the specification beginning at page 42, line 17. Claim 18 has been canceled without prejudice. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed June 14, 2006. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice nonelected claims 7, 11-15 and 17 and amended the claims to be drawn to the elected subject matter. Applicants reserve the right to file a divisional application to all nonelected subject matter.

II. Sequence Rules Compliance

The Examiner suggests that the application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 because sequences set forth in Figures 1-3 and 5 are not followed by a

sequence identifier ("SEQ ID NO:X"). The Examiner suggests that the sequence identifier must be used either in the drawing or in the Brief Description of the Drawings.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to include the sequence identifiers in the Brief Description of the Drawings. Support for this amendment is provided in Example 1a at page 152 of the specification and in particular the table beginning at page 153.

Applicants believe this amendment places the application in compliance with the Sequence Listing Rules.

III. Objection to Drawings

The drawings have been objected to as the Examiner suggests that partial views intended to form one complete view on one or several sheets must be identified by the same number followed by a capital letter. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are submitting herewith corrected drawing sheets referring to the partial views as Fig 1A through Fig. 1I, Fig. 2A through Fig. 2C, Fig. 3A through Fig. 3F and Fig. 5A through Fig. 5B.

Entry of the replacement drawing sheets and withdrawal of this objection is therefore respectfully requested.

IV. Objection to Specification

The specification has been objected to. In particular, the Examiner suggests that the title of the invention is not descriptive as the elected invention is drawn to an isolated nucleic acid. The Examiner suggests that trademarks such as PLATINOL must be capitalized and accompanied by generic terminology. The Examiner suggests that all embedded hyperlinks must be deleted. The Examiner suggests that not all tables are numbered and that the table labeled as Table 1 is confusing because it is not the first table. Finally, the Examiner suggests that the word "form" before the phrase "the same patient" on page 394, line 6 should be --from--.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the title to Isolated Nucleic Acids Relating to Cancer. Applicants have amended the specification to capitalize trademarks such as PLATINOL and insured that generic terminology accompanies the trademark. Applicants have deleted all embedded hyperlinks. Finally Applicants have replaced "from" with --form-- at line 6 of page 394.

Thus, withdrawal of these objections is respectfully requested.

With respect to the Examiner's suggestion that labeling of the

Tables is confusing, reconsideration is respectfully requested. While Table 1 may not be the first table in the specification, it is the first of the data tables of the gene expression analysis consecutively labeled as 1 through 18 and presented in Example 2. Accordingly, Applicants disagree that labeling of the tables is confusing when reviewed in the entirety of the teachings of the specification. Accordingly reconsideration of this objection is respectfully requested.

V. Rejection of Claims 1-6, 8-10, 16 and 18 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph

Claims 1-6, 8-10, 16 and 18 have been rejected under 35 U.S.C. 101 as the Examiner suggests that the claimed invention lacks patentable utility due to it not being supported by a specific, substantial and credible utility or, in the alternative, a well-established utility. Further, these claims have been rejected under 35 U.S.C. 112, first paragraph as the Examiner suggests that since the claimed invention lacks a patentable utility, one skilled in the art would not know how to use the claimed invention.

Applicants respectfully traverse these rejections.

It is respectfully pointed out that the basis for this rejection appears to be based upon a misinterpretation of the data presented in the instant application. Specifically, it appears

that the Examiner may have incorrectly interpreted the results and statistic evaluations of the QPCR experiment for Cln224v1 on pages 392-395.

The statistical evaluations of marker sensitivity and specificity are defined at lines 3-8 of page 394. There it is taught that sensitivity is the ability of marker expression levels to distinguish cancer tissue from non-cancerous tissue while specificity is the presence of marker expression in one tissue versus all others tested.

In the example at pages 392-395, the sensitivity of Cln224v1 for detecting colon cancer in individuals with at least 2-fold increased expression versus normal individuals is 27%. The specificity of Cln224v1 colon tissue expression versus all other tissue expression is 86.47%.

As discussed on page 3, lines 9-19 of the instant specification, many current markers associated with cancer have limitations such as low sensitivity which limits their use for diagnosing cancer. Showing Cln224v1 expression is highly colon tissue specific and that over-expression of Cln224v1 identifies nearly 30% of individuals with colon cancer demonstrates a clear utility for diagnosing, monitoring, staging, imaging and treating cancers of the gastrointestinal tract.

Accordingly, withdrawal of these rejections under 35 U.S.C. 101 and 112, first paragraph, for lack of utility is respectfully requested.

VI. Rejection of Claims 16 and 18 under 35 U.S.C. 112, first paragraph - Lack of Enablement

Claims 16 and 18 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The Examiner suggests that in the instant case, the amount of experimentation required by the skilled artisan in order to practice using the claimed nucleic acid for detecting a risk or presence of cancer in a patient or as a vaccine would require an unpredictable amount of experimentation.

In an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice claim 18 drawn to a vaccine.

Further Applicants have amended claim 16 to be drawn to kit for detecting a nucleic acid of claim 1. As discussed in Section V, supra, the utility of the claimed nucleic acid as a diagnostic marker for cancer is demonstrated by data presented at pages 392-395 of the instant specification. Such data is clearly enabling for the claimed kit for detecting this marker.

Withdrawal of this rejection under 35 U.S.C. 112, first

paragraph is therefore respectfully requested.

VII. Rejection of Claims 1-6, 8-10, 16 and 18 under 35 U.S.C. 112, first paragraph - written description

Claims 1-6, 8-10, 16 and 18 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the claims are drawn to a genus of nucleic acid molecules including any nucleic acid molecule that selectively hybridizes to the nucleic acid of SEQ ID NO:36 or any nucleic acid molecule that encodes the polypeptide of SEQ ID NO:194, which is also encoded by SEQ ID NO:36. The Examiner suggests that since the claims do not specify any stringency conditions for the hybridization, and do not contain any functional limitations, the claims are broad and read on virtually any nucleic acids.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to state that the nucleic acid selectively hybridizes under stringent hybridization and wash conditions. Support for this amendment is provided in the specification beginning at page 42, line 17.

Withdrawal of this rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

VIII. Rejection of Claims 2-6, 8-10, 16 and 18 under 35 U.S.C. 112, second paragraph

Claims 2-6, 8-10, 16 and 18 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner suggests that it is not clear as to what nucleic acid molecule is referred to in the claims since claim 1, from which they depend, refers to multiple different nucleic acid molecules.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to state claim 1(a), 1(b), 1(c) or 1(d).

Withdrawal of this rejection under 35 U.S.C. 112, second paragraph is respectfully requested.

IX. Rejection of Claims under 35 U.S.C. 102(b)

Claims 1-2, 4-6, 8-10 and 16 have been rejected under 35 U.S.C. 102(b) as being anticipated by Oikawa et al. (Biochemical and Biophysical Research Communication, Vol. 142, Pages 511-518). The Examiner suggests that Oikawa et al. discloses a nucleic acid molecule, CEA, comprising a sequence that is about 80% identical to the sequence of SEQ ID NO;36 which would hybridize selectively

under e.g. low or medium conditions to SEQ ID NO:36.

It is respectfully pointed out, however, that the claims have been amended to be drawn to stringent hybridization and wash conditions. Support for this amendment begins at page 42, line 17 of the instant specification.

Since Oikawa et al. does not teach a nucleic acid that hybridizes under stringent hybridization and wash conditions, this reference cannot anticipate the claims as amended.

Withdrawal of this rejection is therefore respectfully requested.

X. Rejection of Claims 1-6, 8-10 and 16-18 under 35 U.S.C. 102(f) and Obviousness-type Double Patenting

Claims 1-6, 8-10 and 16-18 have been rejected under 35 U.S.C. 102(f) over U.S. Patent Application Serial No. 10/558,861. SEQ ID NO:36 is suggested to be identical to SEQ ID NO:52 of U.S. Patent Application Serial No. 10/558,861. The Examiner has advised that rejection can be overcome by amendment of claims to be patentably distinct or by filing a Declaration that the inventive entity for the commonly claimed subject matter is identical.

Claims 1-6, 8-10, 16 and 18 have also been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-10, 16

and 18 of copending Application No. 10/558,861.

As both of these cases are currently undergoing prosecution which may lead to amendment of the claims to be patentably distinct, it is respectfully requested that these rejections be held in abeyance.

XI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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